REMARKS

Claims 1-5, 7-11, 21-24, 26-30, 36-39, 43-45 and 51 are pending. The Applicant herein respectfully requests further examination of the application and reconsideration of the rejection in view of the amendments to the claims and remarks presented as follows.

Rejection under 35 USC §102(b)

The Examiner's stated position is that the present invention, as defined by the claims, is anticipated by the disclosure of Conte, *et al.*, U.S. Patent No. 5,422,123 (Conte, *et al.*,'123).

The Applicant respectfully highlights the fact that each and every limitation expressly required by the language of an accused claim must be present either expressly or inherently in a single prior art reference for a finding of anticipation under 35 USC §102(b). Celeritas Techs. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1360 (Fed. Cir. 1998).

The Applicants respectfully highlight the fact that the disclosure of Conte, *et al.*, describes an effective *diffusion*-release device comprised of a core which swells on contact with aqueous liquids and an elastic coat to accommodate changes in volume due to the hydration and gelling of the core.[1] In contrast, an intended effort is indeed made in the written description of the instant disclosure by the Applicant *not* to use a swellable core and elastic coat tablet composition employed by Conte, i.e., "[s]welling of the polymer, however, can deform the controlled release device and alter the release rates"; "The rate of release from devices with a swellable and/or erodible polymer decrease in the later stages of drug release whereas *dissolution* devices afford constant release throughout the delivery period". Emphasis added.. Page 3 line 11-12; page 7 line 6 to 10.

[1] The Conte core formulation is designed to swell when it imbibes water during dissolution. High molecular weight polymers and cross-linked polymers are specifically required. See, e.g., Conte, *et al.*,'123, col.2, lines 22-23 and 43-51.

1. diffusion vs. dissolution, and other features

In sharp contrast to the disclosure of Conte, *et al.*, the Applicant's invention within the scope of claims 1-5, 7-11, 21-24, 26-30, and 36, for example, requires a dissolution device having a rigid coating wherein the release rate of the active ingredient is determined by the surface area and rate of erosion of the *planar* release face.[2] The core is particularly designed to maintain its dimensions (i.e., not to swell) during dissolution in order to control the surface area of the dissolving front (planar release face).[3] Devices of the Applicant's invention are indeed capable of delivering a constant controlled release -or- a variable controlled release of an active ingredient, depending upon the shape of the core wherein the surface area of the release face increases or decreases during delivery. See , e.g., Applicant's claims 21-22 and FIGs. 2-4. In fact, the two systems operate via vastly different mechanisms, i.e., diffusion vs. dissolution. The Conte, *et al.*, diffusion-release device is comprised of a core which "swells on contact" with aqueous liquids.[4] As is illustrated *infra*, using the data from the Conte examples, the drug rapidly becomes depleted in proximity of the gel surface. The release rate then becomes a function of the diffusion path length through the gel through which the remaining drug must diffuse to reach the exposed surface in contact with the dissolution media. The Applicant particularly points out the mechanistic differences between the devices of claims 1-5, 7-11, 21-24, 26-30, and 36 of the present invention and subject matter within the disclosure of Conte *et al.*, in the release kinetics equations shown at pages 5-6 of the instant specification. The release of drug from tablets made according to Equation 1 is proportional to the surface area of the dissolving face. If the surface area is kept constant (e.g., FIG. 2) the release rate is constant. If the surface area gradually increases (e.g., FIG. 3), the release rate increases accordingly. Conversely, if the area decreases (e.g., FIG. 4), the release rate decreases gradually. The increasing or decreasing rate profiles cannot be achieved using the diffusion mechanism through

[2] See, e.g., pages 5, 15, and 16 of the instant specification.

[3] Dissolution from the surface as in the case of hard boiled candy.

[4] As highlighted, for example, in the instant specification at page 4 lines 14-16, a dissolution device is suitable for formulating hydrophobic and hydrophilic compounds whereas a diffusion device is especially suited to deliver hydrophilic compounds.

swelling gel within the disclosure of Conte, *et al.*,'123.[5] Moreover, the release rate from swellable cores are erratic.[6]

The Applicant graphs the data of the Examples presented within the disclosure of Conte, *et al.*, shown in the Appendix attached hereto, to illustrate the difference in operability of embodiments within the disclosure of Conte, *et al.*, in contrast to embodiments of the present invention.[7] The release profiles indeed show marked differences. The release rates from Conte's devices are not linear as the initial and terminal portions of each release profile departs from linearity due to the initial rapid release from the surface of the swellable core matrix and the increasingly retarded release due to the necessarily increased diffusion path. In contrast, the applicant's profiles demonstrate linearity.[8] In sharp contrast to the release kinetics of embodiment taught within the disclosure of Conte, *et al.*, fundamentally, the release rate from the Applicant's system is *linear*, in fact.

The Applicant further respectfully points out to the Examiner that the coating employed in embodiments taught by the Applicant does not gel, swell, or is not otherwise elastic in any way as required by Conte, *et al.* The Applicant's coating exhibits vastly different properties and functionality. Since the core of the Applicant is non-swelling, a rigid core is obtained, and the coating applied is rigid as well, i.e., "mechanically strong".[9]

In Conte's formulation the coat ("support") swells along with the core. The surface area of the core and the support increase during dissolution process. In contrast the coat in Applicant's embodiments is applied to the core to maintain the dimensions (surface area) of the dissolving face and of the core. The applied coat is rigid, does not swell and maintains its

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[5] Nor does Conte, *et al.*, contemplate or suggest any shape which can achieve controlled variable rate.

[6] See, e.g., Applicant's specification at page 7, lines 6-10.

[7] See, e.g., FIG.6 of the Applicant's written description.

[8] In dissolution embodiments wherein the surface area of the release face is constant throughout delivery.

[9] As indicated at the top of page 16 of the instant disclosure.

structural shape until it disintegrates. Moreover, the example configurations, truncated bipyramid and two frustum of a cone, e.g., FIG.3-4, are unique in the ability to deliver an increasing or decreasing rate of drug delivery as opposed to pseudo zero order release shown in the data of Conte, *et al.*

2. Applicant's diffusion device

In sharp contrast to the disclosure of Conte, *et al.*, the Applicant's invention within the scope of claims 37-39, 43-45 and 51, for example, requires a diffusion-controlled chemical delivery device comprising at least one planar release face *and* a planar dissolution surface wherein the dimensions of the release face remain constant throughout the delivery period. In other words the dimensions of the core remain constant throughout the delivery period while the dissolution surface recedes from the release face.

As described by the Applicant at page 13, lines 1-9 of the specification, the term "diffusion-controlled" refers to the fact that the active ingredient is disposed in an insoluble matrix and the shape and dimensions of the matrix remain substantially unchanged during the delivery period. In a diffusion-controlled device the dissolution surface, where active compound is released into the fluid medium, is within the insoluble matrix and only coincident with the release face at the initial point of delivery. During the release period the dissolution front moves away from the exposed face of the matrix and the active substance released from the dissolution front within the insoluble matrix must diffuse through pores of the insoluble matrix to reach the surface, i.e., "release front", exposed to the fluid medium.[10] The insoluble matrix (core) in a diffusion release device leaves a depleted ghost residue which will be voided intact unless means for disintegration are incorporated into the device.

An embodiment of the Applicant's invention according to claim 37, for example, is illustrated in FIG.3 and FIG.5, for example, wherein the surface area of said dissolution surface increases throughout the delivery period to compensate for an increase in the diffusion path length. An increasing surface area of the dissolution front is effectively exposed during the drug

[10] Further, as described at page 17, lines 4-9, the dependence of the release rate on the area of the dissolution front is given by Equation 2 at page 6 of the written description.

delivery (while the dimensions of the release face (and core overall) remain constant) to achieve an overall constant rate of release.

These are example features of the present invention required by the claims presented herewith that are not described, contemplated or suggested anywhere within the disclosure of Conte, *et al.*

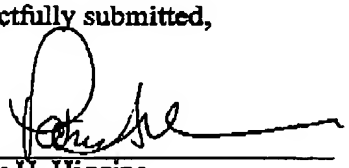
Conclusion

In view of the statutory requirement that each and every limitation expressly required by the language of an accused claim must be present either expressly or inherently in a single prior art reference for a finding of anticipation under 35 USC §102(b), the Applicant respectfully requests the Examiner to withdraw the rejection.

For the foregoing reasons, the Applicant submits that Claims 1-5, 7-11, 21-24, 26-30, 36-39, 43-45 and 51 are in condition for allowance. Early action toward this end is courteously solicited.

The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

Respectfully submitted,



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